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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/856,795 | 08/14/2001 | Arnon Shani | U013484-1 | 3790 |
| 140 | 7590 | 04/21/2004 | EXAMINER | |
| LADAS & PARRY 26 WEST 61ST STREET NEW YORK, NY 10023 | | | JIANG, SHAOJIA A | |
| | | ART UNIT | | PAPER NUMBER |
| | | | | 1617 |

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/856,795 | SHANI ET AL. |
| | Examiner Shaojia A Jiang | Art Unit 1617 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 February 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 53-107 and 109-113 is/are pending in the application.
- 4a) Of the above claim(s) 64-69, 74 and 83-88, 105-106 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 53-63, 70-73, 75-82, 89-104 and 107, 109-113 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on February 2, 2004 wherein claims 53-63, 70-73, 75, and 107 have been amended, and claim 108 is cancelled, and claims 109-113 are cancelled.

Currently, claims 53-107 and 109-113 are pending in this application.

It has been recorded in the previous Office Action, claims 64-69, 74, and 83-88, are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, and claims 105-106 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 53-63, 70-73, 75-82, 89-104 and 107, and new claims 109-113 as amended now are examined on the merits herein.

Applicant's declaration of Shlomo Magdassi (inventor) submitted February 2, 2004 under 37 CFR 1.132, are acknowledged and will be further discussed below.

The following is new rejection(s) necessitated by Applicant's amendment filed on February 2, 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 53 and 112-113 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment submitted February 2, 2004 with respect to amended claim 53 and new claims 112-113 have been fully considered but is deemed to insert new matter into the claims.

The omission of an essential element of the invention "wherein the polymer matrix comprises a protein and a polysaccharide" in claim 53 is deemed to raise new matter issue, i.e., an issue regarding whether the inventor had possession of a broader, more generic invention. See, e.g., >PIN /NIP, Inc. v. Platte Chem. Co., 304 F.3d 1235, 1248, 64 USPQ2d 1344, 1353 (Fed. Cir. 2002). As noted in MPEP 2163, A claim that omits an element which applicant describes as an essential or critical feature of the invention originally disclosed does not comply with the written description requirement. See Gentry Gallery, 134 F.3d at 1480, 45 USPQ2d at 1503; In re Sus, 306 F.2d 494, 504, 134 USPQ 301, 309 (CCPA 1962). In the instant case, "a protein" such as gelatin is considered to be an essential and critical element of the claimed invention, supported by Applicant's declaration of Shlomo Magdassi submitted February 2, 2004 under 37 CFR 1.132.

Moreover, the specification as originally filed does not provide support for "the volatile component is released from the water insoluble bead in atmospheric air over a period comprising a plurality of hours" and "over a period comprising a plurality of days".

The original specification merely discloses "Usually the fluid that is exuded during the first 36 hours, is principally water and only a relatively small amount of volatile material is lost" (see for example fifth paragraph at page 4 of the specification). Nowhere can the recitation "the volatile component is released from the water insoluble bead in atmospheric air over a period comprising a plurality of hours" and "over a period comprising a plurality of days" be found in the specification.

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 53-63, 70-73, 75-82, 89-104 and 107, and new claims 109-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Connick (4,401456) and Nitto Electric Ind Co. (Abstract, JP58121212) in view of Meinke et al. (Journal of Economic Entomology, 1989, Vol 82, 1830-1835) for reasons of record stated in the Office Action dated July 29, 2003.

Connick discloses water insoluble beads in a sustained release polymer matrix comprising droplets of an oil-in-water emulsion in a polymeric matrix (see col.2 lines 45-58 and Examples therein), surface active agents broadly, aliginate (the particular polysaccharide), bioactive material (one volatile hydrophobic component herein), and water; and the process for preparing such a sustained release, polymer, and water insoluble beads therein. Connick also discloses the size of beads therein is 0.1-5 mm, 0.8-2 mm, or 0.1-6 mm; and the gellant is a calcium solution; a bioactive material may be herbicide or insecticide. See abstract, col.1, col.3-4, col.5 lines 1-16, Examples 1-14 and claims 1-11.

Nitto et al. discloses a sustained release, polymer, and water insoluble gel-like body comprising sodium polyacrlate compound having at least one epoxy group per molecule, cationic surfactant, volatile substance which is in emulsion form, and water; the volatile substance which may be a perfume repellent, attractant, insecticide, and fungicide, is used in amount of 30% or less based on the total weight of the body. See abstract.

The prior art does not expressly disclose that the particular surfactant may be a protein such as gelatin, that the particular volatile component may be pheromone such as gosspluer.

Meinke et al. discloses that the particular bioactive material, pheromone, is known to be used in a sustained release, polymer, and water insoluble delivery system for western corn rootworm. See abstract and the entire article.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular surfactant such as a protein (gelatin), and employ the particular volatile component such as pheromone (gosspluer) in the instant claimed beads.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular surfactant such as a protein (gelatin) in the instant claimed beads since gelatin is a well known surfactant and well known in the art to be useful in a sustained release, polymer, and water insoluble delivery system. Moreover, the employment of surfactants broadly is known in the sustained release, polymer, and water insoluble beads of Connick and the sustained release, polymer, and water insoluble gel-like body of Nitto et al. Therefore, one of ordinary skill in the art would have reasonably expected that gelatin would be useful in the delivery systems of Connick and Nitto as a surfactant.

Additionally, one having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular volatile component such as pheromone (gosspluer) in the instant claimed beads since the employment of bioactive material broadly such as a perfume repellent, attractant, insecticide, and fungicide, is known in the delivery systems of Connick and Nitto. Pheromone as herbicide or insecticide is also known to be useful in a sustained release, polymer, and water insoluble delivery system for western corn rootworm. Therefore, one of ordinary skill in the art would have employed the particular volatile component such as pheromone in the instant claimed sustained release system.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Response to Argument

Applicant's arguments and Applicant's declaration of Shlomo Magdassi filed February 2, 2004 with respect to this rejection under 35 U.S.C. 103(a) as being unpatentable over Connick (4,401456) and Nitto Electric Ind Co. (Abstract, JP58121212) in view of Meinke et al. in the previous Office Action have been fully considered but are found persuasive as to the nonobviousness of the claimed invention over the prior art as further discussed below.

Applicant's assertion in regard to (a) an intended use of the claimed product or (b) inherently present in the cited art, citing that "in MPEP Section 2173.054g) ("A functional limitation is often used in association with an element, ingredient or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step."). See, also, *In re Barr*, 170 US/Q 33 (CCPA 1971)" in Applicant's remarks filed March 7, 2003 at paragraph bridging page 5-6, has been considered.

It is the examiner's position that the recitation relating to the atmospheric release characteristics of the claimed water insoluble beads is not considered a limitation to the claimed water insoluble bead since it is well settled that "intended use" of a composition or product, e.g., applying in atmospheric air, will not further limit claims drawn to a composition or product and "released into the atmosphere by evaporation" is also considered to be the inherent property of the composition herein. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161, It is also well settled

that recitation of an inherent property of a composition or method will not further limit claims drawn to a composition or method, as discussed in the previous Office Action.

Note that Applicant cites from MPEP 2173.05(g) and admits that "A functional limitation is often used in association with an element, ingredient or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step."(emphasis added), see *In re Barr*, 170 US/Q 33 (CCPA 1971). Thus, what specific and essential or critical elements, ingredients or components recited in the instant claimed invention to perform this function or intended use is in question and at stake. In order to patentably distinguish the claimed invention from the prior art with respect to a composition or product claimed, the specific and essential or critical ingredients or components in specific amounts which patentably distinguish over the prior art, to give the function have to be recited in the claims. If the prior art teaches those ingredients or components or well known in the art, the prior art compositions are capable of performing the intended use, then it meets the claim. See also *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicant's declaration of Shlomo Magdassi under 37 CFR 1.132, submitted February 2, 2004, is insufficient to overcome this rejection under 35 U.S.C. 103(a) for the following reasons. Applicant's testing results and data shown in the declaration herein have been fully considered but are not deemed persuasive as to the nonobviousness and/or unexpected results of the claimed invention over the prior art.

First, the instant claims are limited to employ a single surfactant agent, gelatine. However, all tests herein merely demonstrate gelatine in different concentration

comparing to 2% Tween-80 (see ID1-6 in the declaration). Thus, the evidence in the testing examples herein is not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the ingredients, i.e., other surfactant agents broadly, e.g., a protein, a monomeric surfactant and a polymeric surfactant recited in claim 57.

Second, note that Shlomo Magdassi states "To test the effects of gelatine on the release rate of pheromones from calcium-alginate based microcapsules and to support the idea that besides being a simple surfactant in the prepared emulsions gelatine also acts as an inhibitor of the pheromone release the following formulations were prepared" (emphasis added, see page 1 of the declaration). Nevertheless, Shlomo Magdassi's statement is seen to be absent any supporting data since the declaration merely presents the release rate of dodecyl acetate from different concentrations of gelatine in microcapsules (see Exhibit 4). One of ordinary skill in the art would recognize that dodecyl acetate and pheromones are neither structurally similar or related to each other, nor have similar properties. Thus, the testing results of dodecyl acetate are not considered to support Shlomo Magdassi's statement above.

Thus, there is no clear and convincing evidence in the declaration for supporting the nonobviousness or unexpected results for the claimed herein over the prior art. Therefore, the declaration is insufficient to rebut the *prima facie* case herein.

Furthermore, as discussed in the previous Office Action July 29, 2003, Applicant's Examples 1-26 herein of the specification at pages 8-16 have been fully considered with respect to the nonobviousness and/or unexpected results of the

claimed invention over the prior art but are not deemed persuasive for the reasons below. These Examples provide no clear and convincing evidence of nonobviousness or unexpected results over the cited prior art since they provide no side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

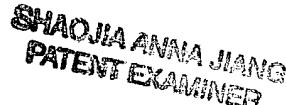
In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.


S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
April 14, 2004


SHAOJIA ANNA JIANG
PATENT EXAMINER